LA-UR -92-1359

Los Alamos National Laboratory is operated by the University of California for the United States Department of Energy under contract W-7405-ENG-36

LA-UR--92-1359

DE92 013526

TITLE Bioethics in America: Who Decides?

AUTHOR(S) Michael S. Yesley, J.D.

SUBMITTED TO Presentation to the Second Bioethics Seminar in Fukui, Japan

DISCLAIMER

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

By acceptance of this article, the publisher recognizes that the U.S. Government retains a nonexclusive, royalty-free license to publish or reproduce the published form of this contribution, or to allow others to do so, for U.S. Government purposes.

The Los Alamos National Laboratory requests that the publisher identify this article as work performed under the auspices of the U.S. Department of Energy

Los Alamos National Laboratory
Los Alamos, New Mexico 87545

MASTER

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

Bioethics in America: Who Decides?

Michael S. Yesley, J.D.
Coordinator, Program on the Ethical, Legal and Social Implications of the Human Genome Project
United States Department of Energy

As an attorney, I am interested in the process by which bioethics decisions are made as well as the actual decisions that are reached. The process commonly is one of "shared decision-making," that is, decisionmaking at several levels, beginning with the government and ending with the individual. After the government has defined a scope of permissible activity, the research or health care institution may further limit what activities are permitted. Finally, the individual patient, or, if the patient is incompetent, the patient's legal representative decides whether or not to participate in the activity.

I should add that this is a general description of the process in the United States. In Japan, there is an additional level at which decisions are made, or perhaps a level that is substituted for a decision by the individual, and that is a decision on behalf of the individual by his or her family.

Where is the scientist in this process? I have not forgotten the scientist. It is he or she who initiates the process by proposing to conduct novel activities intended to help the individual patient and to add to the body of knowledge. Because these activities - particularly in molecular medicine - are novel or may present unknown risks to the patient, society does not leave the decision entirely to the scientist, but

establishes a process in which many share in making the decision whether to proceed, after the scientist has proposed an activity.

Because bioethics in general, and bioethics related to genetics in particular, evolves through this process of decision-making at several levels, I propose to briefly trace the process, to see how it works in several areas of bioethics, in order to provide a perspective on the way in which ethical decisions related to genetics are or will be made.

Before discussing this process, however, I would like to briefly outline a set of principles formulated by the National Commission for the Protection of Human subjects, with which I was associated 15 years ago. These principles are as much descriptive of the process of bioethics as they are prescriptive, that is, the process customarily takes these principles into account, and it would be unwise to fail to do so.

The principles, as enunciated in the Commission's so-called "Belmont Report," are respect for persons, beneficence, and justice. To say just a few words about each, respect for persons has 2 aspects: respecting the autonomy of individuals by requiring their informed consent if they are competent and, if they are incompetent, providing protection by requiring the consent of those who act on their behalf. It appears to me that the involvement of the family in Japan is roughly equivalent to the involvement of the family in the United States when the patient is incompetent. In a way, you treat patients generally

as incompetent, not out of disrespect, but because you rely on the family to determine the patient's best interests.

In order for the patient or the family to make the decision, three elements of informed consent are necessary: sufficient information must be provided, the information must be understood by the patient or family, and the decision whether to participate in the research or course of treatment must be voluntary.

The principle of beneficence may be expressed as the traditional "Do no harm" plus a utilitarian ethic of maximizing possible benefits and minimizing possible harms. Justice requires fairness in the distribution of health care and the selection of research subjects. Those who share the risks should also share the benefits.

Turning to the broadest level of bioethics decisionmaking - the government, we note the three branches in the United States: the legislature, that is, Congress, the judiciary, most significantly the Supreme Court, and the Executive Branch, which administers the laws passed by Congress within the statutory and constitutional limits enunciated by the courts.

Congress may act in several ways, most notably by the appropriation of funds and the imposition of controls. An example of bioethics by appropriation is the decision to fund the Human Genome Project - certainly a matter of scientific policy but also a determination that public monies should be allocated to this effort in order to gain a public good.

Among the controls imposed by Congress that have bioethics aspects are the requirement that human experimentation must be reviewed by an institutional review board, the recent Patient Self-Determination Act that requires hospitals to inform all incoming patients of their right to direct that they be allowed to die under certain circumstances, and the Americans with Disabilities Act, also recent, which prohibits discrimination against those who are disabled. I should note that the requirement that human experimentation be reviewed is a good example of shared decisionmaking: the federal government requires the review, the research institution conducts the review, and, if the research is approved, the subject decides whether or not to participate. I should also note that the Patient Self-Determination Act may be superfluous in a country such as Japan, where the determination is made by the patient's family.

Congress may act in another way when it is not certain what to do about a bioethics or other issue: it may establish an advisory commission to study the issue and then make recommendations for legislation or regulation. In this way, bioethics decisionmaking is shared even further, by the members of the advisory commission. Among the advisory commissions that have operated in the United States are the national commission that focused on guidelines for research with human subjects, the president's commission that made recommendations on the definition of death and other issues, and the so-called ELSI Working Group - not actually a commission - that is providing advice on

the ethical, legal and social implications of the Human Genome Project. (More about ELSI, later.)

Turning to the judiciary, particularly the United States Supreme Court, I would note - without discussion - the decisions regarding abortion, a judicial area that continues to change, and the right-to-die decision involving Nancy Cruzan, an unfortunate young woman who was maintained in an irreversible comatose condition for several years after a car accident. The Cruzan decision is another instance of shared decisionmaking, in which the courts decided the level of evidence that would be required to be presented by Nancy's family to indicate what Nancy herself would have chosen if she were able to contemplate her condition. The Cruzan decision might be unnecessary in Japan, where the family is expected to make that decision for the patient.

In discussing the role of the judiciary, I should note that the courts of our states also make bioethics decisions. For example, a state court decided that "custody" of IVF-fertilized cryo-preserved ova would be shared by a divorced couple, and that the former wife could not make a unilateral decision to have the ova implanted in her. The state courts also make decisions about "wrongful birth" and "wrongful life" -- the former being the claim of the parents for the costs of raising a child whose genetic disorder a physician failed to diagnose. "Wrongful life" is the claim of the child itself for the damage of having been born in a genetically impaired condition. As a matter of law, the state courts generally allow parents' claims for "wrongful birth" on

the grounds that the costs could have been avoided if there had been a correct diagnosis. But the courts disallow the child's "wrongful life" claim on the grounds that there is no damage from being born - even in an impaired condition - as opposed to not being born at all.

The state courts have also been called upon to decide disputes over surrogate motherhood. In the famous case of "Baby M" four years ago, a state court decided that a contract to be artificially inseminated and then give up the child to its genetic father and his wife was unenforceable because it violated the equal rights of the natural (surrogate) mother concerning her child. But the court also found that it was in the best interests of the child to be raised by the natural father and his wife, who were awarded custody subject to liberal visitation rights of the natural mother.

In a more recent case, however, where an IVF embryo was implanted in the surrogate mother, the contract for her to carry and deliver the child, then surrender her maternal rights to the child's genetic parents was enforced. The crucial difference from the Baby M case was this surrogate mother's lack of a genetic relationship with the infant.

Two other recent state court bioethics decisions did not involve reproduction. One involved the unauthorized use of a patient's tissue - the court decided the patient did not have a property right in tissue taken for treatment purposes, but that the researcher had violated the patient's right to give or

withhold his consent to the use of his tissue for research. In another case, the father of illegitimate 3-year-old twins who lived with their mother was denied a court order that the twins submit to bone marrow harvesting against the wishes of their mother to donate to a half-brother suffering from leukemia.

Bioethics decisions are also made by agencies of the executive branch of government. For example, the Public Health Service prohibits federally-funded fetal research, on the grounds that the prospect of such research might influence women to have abortions. In response to this decision by the executive branch, Congress recently voted to end the ban on fetal research, and two medical societies are establishing a national board to develop voluntary guidelines for privately funded fetal research. It's unclear at present who will decide this issue finally.

Another agency - the Centers for Disease Control - is dealing with the question of whether to require that health care providers be tested for AIDS, in the aftermath of the dentist who infected 5 patients.

Many agencies are involved in issues related to genetics, including the Food and Drug Administration, the Recombinant DNA Advisory Committee, and the ELSI activities that I mentioned before. Most of these agencies are involved not only in issues of safety and efficacy, but also of the social acceptability of genetic research activities and, in the case of ELSI, the broad social implications of advances in genetic knowledge.

The ELSI effort is actually composed of several activities. There is a working group of seven advisors who meet three times a year, and also a multi-million dollar program to provide grants for academic research and public educational activities related to the ethical, legal, and social implications of the Human Genome Project. Although these activities have been in process for two years, I would characterize most of them as efforts to learn more about such issues as employment and insurance discrimination, privacy rights including the right not to know, and the integration of genetics into health care delivery. After this information has been developed, we will be in a better position to determine who decides the appropriate course of action for society in the genetic age.

In closing, I would like to acknowledge the challenge of decision-making on an international level. The increasing interdependence of nations and potential impact of the Human Genome Project on the human species have led to calls for an international ELSI policy. However, cultural and economic differences among nations will greatly complicate any effort to achieve a uniform policy for all. Perhaps the experience of the United States, a culturally and economically diverse nation, can provide a model for international approaches.

In the United States, we have identified broad principles, such as the Bill of Rights, and broad boundaries of acceptable activity to which nearly all can agree. On a less lofty level than the Constitution, the principles enunciated in the Belmont

Report have achieved general acceptance among those who conduct or review human experimentation. However, the detailed rules or mode of implementation of broad principles often varies from one state to another in our "laboratory of the states" or from one institutional review board to another, according to different values and preferences for administration. This latitude is built into the system; there is no need to achieve complete uniformity. In this fashion, decisionmaking is shared at different levels of government and between the government, private institutions and individuals.

Perhaps this simple model is appropriate for international approaches to the ethical issues raised by increases in genetic information. It is probably not feasible to produce a detailed set of guidelines to which all nations can subscribe. But, again, there is no need for complete uniformity. We can profitably aim for international agreement on broad principles to guide the development and use of genetic information - to protect human rights and assure access to health care, and to guard the future of the human species - while preserving decisionmaking responsibilities of different nations that will accommodate their unique cultural and economic requirements.